IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

UNITED STATES OF AMERICA,

Plaintiff,

v. **CRIMINAL NO. 1:18CR1-2**
(Judge Keeley)

GEORGE P. NAUM, III,

Defendant.

MEMORANDUM OPINION AND ORDER DENYING
DEFENDANT'S MOTION FOR A NEW TRIAL [DKT. NO. 345]

On April 30, 2019, following a six-day trial, a jury convicted the Defendant, George P. Naum, III ("Naum"), of one count of conspiracy to distribute controlled substances outside the bounds of professional medical practice, in violation of 21 U.S.C. §§ 841(a)(1), 841(b)(1)(C), 841(b)(1)(E)(iii), and 846, as charged in Count Twenty-Two of the Indictment, and four counts of aiding and abetting the distribution of controlled substances outside the bounds of professional medical practice, in violation of 21 U.S.C. §§ 841(a)(1), 841(b)(1)(C), and 841(b)(1)(E)(iii) and 18 U.S.C. § 2, as charged in Counts Twenty-Four, Twenty-Five, Twenty-Seven, and Twenty-Eight of the Indictment (Dkt. Nos. 322, 323). Post trial, Naum moved for a new trial pursuant to Federal Rule of Criminal Procedure 33 (Dkt. No. 345). For the reasons that follow, the Court **DENIES** the motion (Dkt. No. 345).

MEMORANDUM OPINION AND ORDER DENYING DEFENDANT'S MOTION FOR A NEW TRIAL [DKT. NO. 345]

I. BACKGROUND

On January 9, 2018, a grand jury sitting in the Northern District of West Virginia returned a fifty-count indictment, charging Naum with one count of conspiracy to distribute controlled substances outside the bounds of professional medical practice, in violation of 21 U.S.C. §§ 841(a)(1), 841(b)(1)(C), 841(b)(1)(E)(iii), and 846 (Count Twenty-Two), and ten counts of aiding and abetting the distribution of controlled substances outside the bounds of professional medical practice, in violation of 21 U.S.C. §§ 841(a)(1), 841(b)(1)(C), and 841(b)(1)(E)(iii) and 18 U.S.C. § 2 (Counts Twenty-Three through Thirty-Two) (Dkt. No. 1).[1]

Naum's jury trial began on April 23, 2019, and lasted six days (Dkt. Nos. 301, 323). The evidence included testimony from numerous witnesses called by the Government, including Diversion Investigator Guy McCartney, Special Agent Matthew Eagles, Corporal John W. Smith, Dr. Patrick Marshalek, codefendants Sharon Jackson ("Jackson") and Eric Drake ("Drake"), and several former patients, W.E., N.H., and N.S. (Dkt. No. 372 at 3).

[1] On April 22, 2019, the Court dismissed with prejudice Counts Twenty-Three, Twenty-Nine, Thirty, Thirty-One, and Thirty-Two as to Naum (Dkt. Nos. 291, 297).

On June 14, 2019, Naum timely filed his motion for a new trial (Dkt. No. 345). The motion was fully briefed as of August 23, 2019, and is now ripe for disposition.

II. LEGAL STANDARD

Under Federal Rule of Criminal Procedure 33, a court may vacate a criminal conviction and grant a new trial "if justice so requires." However, "a trial court should exercise its discretion to award a new trial sparingly, and a jury verdict is not to be overturned except in the rare circumstance when the evidence weighs heavily against it." United States v. Smith, 451 F.3d 209, 217 (4th Cir. 2006); United States v. Munoz, 605 F.3d 359, 373 (6th Cir. 2010) ("The paradigmatic use of a Rule 33 motion is to seek a new trial on the ground that the jury's verdict was against the manifest weight of the evidence." (cleaned up)). "Further, courts have 'widely agreed that Rule 33's interest of justice standard allows the grant of a new trial where substantial legal error has occurred.'" United States v. Smithers, No. 1:17CR00027, 2019 WL 3456625, at *2 (W.D. Va. July 31, 2019) (quoting Munoz, 605 F.3d at 373). But "any error, defect, irregularity, or variance that does not affect substantial rights must be disregarded." Fed. R. Crim. Pro. 52(a).

III. DISCUSSION

Naum's motion contends that the interests of justice require a new trial because (1) the Government was required to prove that the prescriptions Naum issued were without a legitimate medical purpose; (2) the Government presented insufficient evidence to sustain its burden of proof; and (3) the Court committed substantial legal error by excluding evidence of the Massachusetts and Vermont models of treatment (Dkt. Nos. 345, 359). As discussed further below, the Court finds that the Government satisfied its burden of proof and that no substantial legal error occurred. It therefore **DENIES** Naum's motion (Dkt. No. 345).

A. The Government was not required to prove that Naum's prescriptions were issued without a legitimate medical purpose.

Naum contends that a new trial is required because the Government never introduced evidence to establish that his prescriptions were issued without a legitimate medical purpose (Dkt. Nos. 345 at 5-7, 359 at 22-29). This argument, however, is based on a fundamental misunderstanding of the relevant statutory language and controlling Fourth Circuit precedent.

"To convict a physician of distributing a controlled substance in violation of [21 U.S.C.] § 841, the Government must prove the

following three elements." United States v. Singh, 54 F.3d 1182, 1186-87 (4th Cir. 1995). "First, it must show that the defendant 'distributed or dispensed a controlled substance.'" Id. at 1187 (quoting United States v. Tran Trong Cuong, 18 F.3d 1132, 1141 (4th Cir. 1994)). "Second, it must prove that, in doing so, 'he acted knowingly and intentionally.'" Id. (quoting same). Third, "the evidence must show that the defendant's 'actions were not for legitimate medical purposes in the usual course of his professional medical practice or [were] beyond the bounds of medical practice.'" Id. (alteration in original) (emphasis added) (quoting same). "While the government may meet its burden of proving guilt by showing that a physician dispensed a controlled substance for an illegitimate purpose, the government is not required to make such a showing." United States v. Hitzig, 63 F. App'x 83, 87 (4th Cir. 2003) (citing Singh, 54 F.3d at 1188).

Under the Fourth Circuit's decisions in Singh, Tran Trong Cuong, and Hitzig, the Government may prove the third element of the offense by showing that Naum's actions either were (1) not for legitimate medical purposes or (2) beyond the bounds of medical practice. Every other circuit court to address this question has reached the same conclusion. See United States v. Merrill, 513 F.3d

1293, 1306 (11th Cir. 2008) (holding a doctor has violated § 841 when the government has proved beyond a reasonable doubt that the doctor's actions were not for legitimate medical purposes in the usual course of professional medical practice or were beyond the bounds of professional medical practice); United States v. Nelson, 383 F.3d 1227, 1231-32 (10th Cir. 2004) ("A practitioner has unlawfully distributed a controlled substance if she prescribes the substance either outside the usual course of medical practice or without a legitimate medical purpose." (emphasis added)); cf. United States v. Boettjer, 569 F.2d 1078, 1081 (9th Cir. 1978) (holding both a "legitimate medical purpose" and "usual course" must be met for a prescription to be validly issued).

Naum further contends that, to sustain a conviction under § 841, the Government was effectively required to prove "that he had abandoned the practice of medicine and was acting as a drug pusher" (Dkt. No. 359 at 29). But the cases he cites in support do not compel that conclusion. For example, in United States v. Moore, 423 U.S. 122, 124 (1975), the Supreme Court addressed "whether persons who are registered under the Controlled Substances Act . . . can be prosecuted under § 841 for dispensing or distributing controlled substances." Reversing the court below, the Court

unequivocally held "that registered physicians can be prosecuted under § 841 when their activities fall outside the course of professional practice." Id. (emphasis added). This holding, however, never limited § 841 prosecutions to physicians who dispensed or distributed controlled substances without a legitimate medical purpose. Id. In fact, the Court further concluded that "[t]he evidence presented at trial was sufficient for the jury to find that [the defendant]'s conduct exceeded the bounds of 'professional practice.'" Id. at 142 (emphasis added) (footnote omitted). In support of that conclusion, the Court listed the numerous ways in which the defendant's actions exceeded the bounds of professional practice and concluded, "[i]n practical effect, he acted as a large-scale 'pusher' not as a physician." Id. at 143. Put in its proper context, this statement is nothing more than dicta expressing an opinion, and in no way compels a standard of proof that the Government must prove Naum acted as a "drug pusher."

Relying on United States v. Goldstein, 695 F.2d 1228 (10th Cir. 1981), Naum next contends that, "[e]ven where there may be a statutory violation, a physician cannot be convicted for a violation of 21 U.S.C. § 841 if the prescriptions were issued for a legitimate medical purpose" (Dkt. No. 359 at 26). This is simply

not so. Indeed, the United States Court of Appeals for the Tenth Circuit—the court that authored the Goldstein opinion—has concluded otherwise: "A practitioner has unlawfully distributed a controlled substance if she prescribes the substance either outside the usual course of medical practice or without a legitimate medical purpose." Nelson, 383 F.3d at 1231-32 (emphasis added).

This leads to the inescapable conclusion that, even absent evidence that Naum's prescriptions were issued without a legitimate medical purpose, the Government had only to prove that his actions were "beyond the bounds of medical practice." Tran Trong Cuong, 18 F.3d at 1141; see also Singh, 54 F.3d at 1188 ("[A]lthough the testimony does not adduce compelling evidence that [the defendant] prescribed with malicious motive or the desire to make a profit, those motivations, though common in § 841(a)(1) prosecutions, are not required to convict."). Because the Government needed only to prove Naum's actions were beyond the bounds of medical practice, any evidence of a legitimate medical purpose was irrelevant and therefore inadmissable. See Fed. R. Evid. 402 ("Irrelevant evidence is not admissible.").

"Evidence is relevant if: (a) it has any tendency to make a fact more or less probable than it would be without the evidence;

and (b) the fact is of consequence in determining the action." Fed. R. Evid. 401. Determining whether evidence is relevant is fundamentally a matter of trial management. United States v. Reed, 884 F.3d 230, 235 (4th Cir. 2018). Here, evidence of a legitimate medical purpose had no tendency to make the question whether Naum was acting outside the bounds of medical practice more or less probable. Fed. R. Evid. 401(a). Nor was it a fact of consequence for determining whether he exceeded the bounds of medical practice. Fed. R. Evid. 401(b).

Consider, for example, a patient who has a legitimate medical need for suboxone because he is, in fact, suffering from opioid use disorder. A physician may still be convicted under § 841 for dispensing or distributing suboxone to this patient because——despite the patient's legitimate need——the physician performed an inadequate or cursory examination, if he performed one at all; never diagnosed the patient with opioid use disorder; did not perform an examination on return visits; ignored test results (e.g., inconsistent drug screens); took little or no precautions against misuse or diversion; did not regulate dosage; charged the patient based on the desired prescription without authorizing refills, requiring him to return and pay to obtain a new

prescription; and issued prescriptions without establishing a bona fide doctor-patient relationship. In other words, despite the patient's legitimate need, the physician acted beyond the bounds of medical practice and violated § 841. The same holds true here. Thus, evidence of a legitimate medical purpose was irrelevant and therefore inadmissible under Federal Rule of Evidence Rule 402.

Naum insists that, by excluding this evidence, the Court prevented him from putting on a defense. He further contends that the Court was biased for enforcing its pretrial rulings without objection from the Government (Dkt. No. 359 at 30-31). Both arguments lack merit.

Although the Court's pretrial rulings did not relieve the parties of the need to object in order to properly preserve issues for appellate review, the Court need not wait for an objection to enforce its own pretrial rulings during trial. Cf. United States v. Smith, 441 F.3d 254, 268 (4th Cir. 2006) (finding no error when district court interrupted cross examination without objection); see also United States v. Reed, 641 F.3d 992, 995 (8th Cir. 2011) (concluding that a "stern admonition . . . was in order" when defense counsel asked a question that would violate the court's pretrial ruling). Indeed, "[a] district court is . . . vested with

broad authority to control the manner of trial and the presentation of evidence." United States v. Seigel, 536 F.3d 306, 320 (4th Cir. 2008) (citing United States v. Janati, 374 F.3d 263, 273 (4th Cir. 2004) ("The scope of the district court's discretion to manage trials before it is and must be particularly broad.")); see also Fed. R. Evid. 611(a). Moreover, the Court was not biased simply because it enforced a pretrial ruling with which Naum had disagreed——and repeatedly challenged——throughout the case (Dkt. Nos. 255; 273 at 4; 279; 370 at 30; 371 at 20-29, 33-35; 359 at 22-29). See, e.g., Botts v. United States, 413 F.2d 41, 44 (9th Cir. 1969) ("Unfavorable rulings in the same case do not constitute nor demonstrate the judge's bias and prejudice.").

Nor did excluding this evidence prevent Naum from putting on his good-faith defense (Dkt. No. 371 at 33-35). Although precluded from introducing irrelevant evidence of legitimate medical purpose, Naum was free to admit evidence, including expert testimony, to show his good faith belief that he was acting within the bounds of professional medical practice. Indeed, this Court gave the jury the following instruction:

> A physician cannot be convicted of conspiring to unlawfully distribute suboxone or aiding and abetting the unlawful distribution of suboxone if he acted in good faith in issuing the prescription. Good faith in this context is not merely a physician's

> sincere intention towards the patients who come to see him. Rather, it involves his sincerity in attempting to conduct himself in accordance with a standard of professional medical practice generally recognized and accepted in the country. Thus, it indicates an observance of conduct in accordance with what the physician reasonably believed to be proper medical practice.
>
> The defendant does not have to prove that he acted in good faith. The burden of proof remains on the Government at all times to prove to you beyond a reasonable doubt that the defendant conspired to distribute suboxone outside the bounds of professional medical practice, as charged in Count Twenty-Two in the Indictment, and aided and abetted the distribution of suboxone outside the bounds of professional medical practice, as charged in Counts Twenty-Four through Twenty-Eight in the Indictment.
>
> In considering whether the defendant acted in good faith, you should consider the defendant's actions and all the facts and circumstances in the case. If you find that the defendant acted in good faith, then you must find him not guilty.

(Dkt. No. 319 at 34-35). As this instruction makes clear, Naum was not precluded from presenting evidence, and arguing to the jury, that he was acting within the bounds of professional medical practice in good faith.

In sum, the Government was not required to prove that Naum issued prescriptions to patients without a legitimate medical

purpose. Accordingly, no substantial legal error occurred requiring a new trial.

B. The Government presented sufficient evidence at trial for a reasonable jury to conclude that Naum's actions were beyond the bounds of professional medical practice.

Naum next contends that the Government attempted to prove that he acted outside the bounds of professional medical practice because he violated a West Virginia state disciplinary regulation, which was not in effect until halfway through the conspiracy alleged in Count Twenty-Two of the Indictment (Dkt. No. 359 at 31-32). He asserts that a violation of an applicable state regulation is legally insufficient and that he relied in good faith on the dismissal order from the West Virginia Board of Osteopathic Medicine ("WVBOM"), which he contends absolved his medical practice at Advance Healthcare, Inc. ("Advance") of any violations. Id. at 32-33. At bottom, he argues that the Government failed to introduce sufficient evidence to sustain its burden of proof at trial. Id. at 31-33. He claims that to hold otherwise would turn a regulatory or disciplinary violation into a strict-liability crime under federal law. Id. at 33. Each of these arguments is without merit.

As Naum concedes, the Government may satisfy its burden of proof by showing that a physician, for example: (1) performed

inadequate or perfunctory examinations, or none at all; (2) did not perform examinations on return visits; (3) ignored test results; (4) took little or no precautions against misuse and diversion; (5) did not regulate dosage; (6) charged patients based on desired prescriptions without authorizing refills, requiring patients to return and pay to obtain new prescriptions; and (7) issued prescriptions without establishing a bona fide doctor-patient relationship (Dkt. No. 359 at 23-26).

Here, the Government presented more than sufficient evidence to sustain its burden of proof. At Advance, where Naum practiced and served as "medical director" (Dkt. No. 372 at 681, 709), patients were required to pay with cash or credit card at every visit (Dkt. No. 372 at 212-14). They also were required to "come in and pay for an office visit every time they got a new script" (Dkt. No. 372 at 238). If a patient could not afford the $125 fee for their follow-up appointment, they could pay half and "get half of their prescription." Id. at 213. In other words, the patient's payment was not based on medical services rendered, but rather on the amount of drugs a patient could afford at any given time.

In addition, Naum's physical examinations, if any, were often inadequate or perfunctory. For example, his examination of an

undercover officer——who was not suffering from opioid use disorder——lasted less than three and a half minutes and did not include any kind of "physical" examination. Id. at 179-80; Gov. Exh. 55. As well, Naum failed to perform a physical examination of W.E., whom he saw only once (Dkt. No. 372 at 396-97). Moreover, Naum never met with patients N.S., N.H., or J.S., let alone conducted physical examinations, before they received prescriptions for suboxone. Id. at 264-65, 410-13, 422-23. Another patient, P.C., testified that he thought Jackson, the registered nurse at Advance, was his doctor. Id. at 434.

But that is not all. Naum, who was a "DATA-waived physician" pursuant to 21 U.S.C. § 823(g)(2) (known as DATA 2000), delegated his authority to dispense suboxone to Jackson, knowing she was neither trained to diagnose opioid use disorder (Dkt. No. 372 at 223), nor authorized to dispense subxone under § 823(g)(2) (Dkt. No. 347 at 3 n.1). Indeed, at trial, Jackson testified that, to be prescribed suboxone, patients needed to have "an opiate addiction" (Dkt. No. 372 at 223). Although she regularly "diagnosed" patients at Advance with opiate addiction (now known as "opioid use disorder"), Jackson conceded that she could not "articulate . . . the criteria for diagnosing an opiate addiction." Id. This is

markedly different from using the diagnostic criteria set forth in the DSM-IV or DSM-V to diagnose opioid use disorder, including the severity of that disorder. Id. at 542. Despite Jackson's lack of medical training and legal authorization, Naum delegated to her the authority to diagnose patients with opioid use disorder, prescribe suboxone for them using his DEA registration number, id. at 222-24, and even to alter patients prescriptions against his written instructions, id. at 232-35.

After reviewing this evidence, the Government's expert, Patrick Marshalek, M.D. ("Dr. Marshalek"), testified that, in his opinion, Naum did not establish or have an ongoing doctor-patient relationship with his patients at Advance and, therefore, the prescriptions issued there were beyond the bounds of medical practice. According to Dr. Marshalek, it was remarkable that, although Naum had seen patient W.E. during her initial visit on September 9, 2014, he never saw her again for over a year, if not longer, even though, throughout that time, W.E. continued receiving prescriptions for suboxone, id. at 537-38, including a prescription that was decreased from 6 to 4 mg a day against Naum's written instruction, id. at 546-47.

Naum's "relationship" with patient N.S. was no different.

Although N.S. never saw Naum during her initial visit, id. at 422-23, Jackson, using Naum's DEA registration number, called in a prescription of suboxone for her. Id. at 551-52. Because Naum had not seen the patient, Dr. Marshalek testified that her prescription was outside the bounds of medical practice. Id. at 552. Although Naum did see N.S. six days later, he never conducted a physical examination to assess her condition or documented that she met the criteria for opioid use disorder. Id. at 552-54. Even more, Naum never saw N.S. again. Although N.S. discontinued her treatment for a period of time, she later returned to Advance where she received another suboxone prescription from Jackson, although she had not seen Naum for close to two years. Id. at 556, 558-60. According to Dr. Marshalek, this prescription was outside the bounds of professional medical practice.

Likewise, as to patient N.H., there was no documentation in his medical chart of a face-to-face meeting with Naum. Id. at 561-62. Nor was there documentation that Naum (or Jackson) had diagnosed N.H. with opioid use disorder using the criteria of the DSM-V. Id. at 562-63. Like patients W.E. and N.S., Naum simply signed off on prescriptions Jackson wrote for N.H., even though the dosage prescribed was inconsistent with his prior instructions. Id.

at 563.

Dr. Marshalek also testified that none of the patient charts that he reviewed evinced any documentation of "pill counts," a common practice for monitoring for, and preventing, misuse or diversion of suboxone. Id. at 535, 555, 589. Jackson too confirmed that the doctors at Advance, including Naum, were not conducting pill counts and regularly ignored inconsistent drug screens. Id. at 240-42.

In short, the Government presented evidence that Naum routinely performed inadequate or perfunctory examinations, if he saw the patient at all; did not perform examinations on return visits; ignored drug test results; took few if any precautions against misuse or diversion; did not regulate dosage; charged patients based on desired prescriptions for suboxone without authorizing refills, thereby requiring patients to pay each time they needed new prescriptions; and issued prescriptions for suboxone without establishing a bona fide doctor-patient relationship. Moreover, he delegated his prescription-writing authority to a registered nurse who was neither trained to diagnose opioid use disorder, nor authorized to dispense subxone under § 823(g)(2).

Ignoring all of this evidence, Naum argues that he relied in

good faith on the WVBOM dismissal order and, at most, did no more than violate a state disciplinary regulation (Dkt. Nos. 345, 359). The jury rejected this defense. First, the Court instructed the jury that "[a] violation of a professional regulation does not in and of itself establish a violation of the criminal law" (Dkt. No. 319 at 35). Second, the Government's evidence established that Naum did far more than violate a state disciplinary regulation. Third, Jackson's testimony demonstrated that the WVBOM dismissal order fell far short of absolving Naum's practices at Advance. Indeed, Jackson testified that much, if not all, of the information reported to the WVBOM in response to its investigation and discussed in its dismissal order was, in fact, false (Dkt. No. 372 at 365-68). This was confirmed by the testimony of Diana Shepard, the Executive Director of the WVBOM, who testified that the Board issued its dismissal order based on statements by Naum that she now understood to be false. Id. at 799-801.

After careful consideration, the Court concludes that the evidence supports the jury verdict. See Smith, 451 F.3d at 217 ("[A] jury verdict is not to be overturned except in the rare circumstance when the evidence weighs heavily against it.").

C. The Court did not err by excluding irrelevant, misleading, and confusing expert testimony.

Finally, Naum contends that the Court erred in violation of his substantial rights when it precluded his expert, Staniford Helm, II, M.D., from testifying about two alternate treatment models used in Massachusetts and Vermont to treat opioid use disorder (Dkt. No. 359 at 33-41). He argues that exclusion of this evidence effectively prevented him from establishing that his practice complied with a standard of medical practice generally recognized and accepted in the country and, thus, precluded him from putting on an effective good-faith defense. Id. This argument fares no better.

First, the Court never excluded evidence of the Vermont model over Naum's objection because he abandoned his effort to establish its relevance and admissibility during a pretrial hearing on April 22, 2019 (Dkt. No. 371 at 39, 53-54, 58). And for good reason: Naum's practice protocols at Advance did not remotely resemble the alternative treatment model used in Vermont and approved by Medicaid. See State of Vermont Blueprint for Health: Hub and Spoke, https://blueprintforhealth.vermont.gov/about-blueprint/hub-and-spoke (last visited Sept. 26, 2019). This so-called "hub and spoke" treatment model arranges treatment services into a network

consisting of a "hub" that offers a full array of treatment services, which is then complimented by a number of smaller "spokes" that offer limited treatment services. Id. It is designed so that, if a patient needs more intense treatment, spokes are able to direct these patients to the hub. Id. Conversely, as a patient stabilizes and requires less intense treatment, the hubs can refer these patients to the spokes for more efficient and localized care. Id.

Under this model, each "hub" is organized around an existing Opioid Treatment Program ("OTP"), that has prescriptive authority to dispense methadone under 21 U.S.C. § 823(g)(1). See id.; see also 42 C.F.R. § 8.2 (defining OTPs as "program[s] or practitioner[s] engaged in opioid treatment of individuals with an opioid agonist treatment medication registered under 21 U.S.C. 823(g)(1)"). Then, DATA-waived physicians who can prescribe suboxone under § 823(g)(2) operate as the "spokes." See id. Here, there was no evidence that Naum's practice at Advance was operating as a "spoke" in a coordinated hub and spoke model, shuffling patients to and from an OTP. Therefore, because the Vermont model was plainly not relevant to his case, and because prior to trial he abandoned his attempt to admit the Vermont model (Dkt. No. 371 at 39, 53-54, 58), and never sought to introduce it during trial (Dkt.

No. 372), Naum cannot now be heard to claim that the Court committed substantial legal error warranting a new trial.

In contrast, the Court did exclude the Massachusetts model at the April 22, 2019 hearing after finding that evidence of that model could mislead and confuse the jury, and would not be helpful to the jury in resolving the issues in the case (Dkt. No. 371 at 54). Naum, however, claims that the Court excluded evidence of the Massachusetts model (and the Vermont model) because evidence of the model practices invited jury nullification (Dkt. No. 359 at 35). This argument mischaracterizes the record.

At the hearing on April 22, 2019, the Court stated that it would not permit Naum, through expert testimony, to introduce evidence of the Massachusetts model in an attempt "to persuade this jury that that [model] is, in fact, the model that Dr. Naum had, which we know it wasn't" (Dkt. No. 371 at 54). To do so, it concluded, would be misleading, confusing, and any probative value would be outweighed by its prejudicial effect. See id. It then confirmed that any attempt to compare Naum's practice at Advance with the model in Massachusetts to which the United States Department of Health and Human Services had granted special permission to operate would go far beyond the facts of the case and mislead the jury. Id. at 58.

Notably, however, this ruling did not preclude Naum from establishing a good-faith defense. Indeed, immediately after excluding evidence of the Massachusetts model, the Court clarified its ruling as follows:

> So the ruling is Dr. Helm may testify as an expert and offer opinions in this case about Naum's use of Nurse Jackson, and whether that practice model at the Naum clinic, with the use of the nurse, the registered nurse, was consistent with Dr. Helm's understanding, knowledge, of practice protocols in the [office-based addiction treatment] area for use of nurse or physician extenders. Is that clear?

Id. at 59. Naum's counsel replied, "Yes, your honor." Id. Only after ruling on the admissibility of the Massachusetts model did the Court then turn to separately take up the question of jury nullification. Id. at 81, 88-89. At that time, Naum confirmed that he did not intend to pursue "the argument . . . that the Government's conduct in this case has had a chilling effect on the availability of treatment." Id. at 89.

The record makes clear that the Court did not exclude the Massachusetts and Vermont models because they invited jury nullification. Rather, Naum abandoned the relevance and admissibility of the Vermont model before trial, and the Court excluded evidence of the Massachusetts model under Federal Rule of Evidence 403 because its probative value, if any, was substantially

outweighed by the danger that it could mislead and confuse the jury.

The correctness of this ruling is underscored by the stark differences between the Massachusetts model and Naum's practice protocol at Advance. The Massachusetts model is a "model of service delivery for facilitating access to life-saving treatment and improving treatment outcomes in patients with opioid use disorders" (Dkt. No. 267-6 at 2). "The key to this model is the interprofessional collaboration between the nurse, provider and other members of the care team to provide comprehensive care during all phases of treatment, including: patient screening, assessment, education, care planning, medication induction, stabilization, and maintenance." Id.

Unlike Naum's practice at Advance, the Massachusetts model requires qualified providers[2] (limited to physicians, physician assistants, and nurse practitioners) to obtain legal authority to prescribe controlled substances to treat opioid use disorder. Id. at 4. At Advance, by contrast, Naum——a DATA-waived physician and, therefore, a qualified provider——delegated his legal authority to

[2] Although the Massachusetts model uses the term "qualified provider," the statute governing DATA-waived practitioners uses the term "qualified practitioner" and "qualified other practitioner." See 21 U.S.C. §§ 823(g)(2)(G)(iii)-(iv) (defining "qualified practitioner").

dispense or distribute suboxone to Jackson, a registered nurse and non-qualified provider. See 21 U.S.C. §§ 823(g)(2)(G)(iii)-(iv) (defining "qualified practitioners" and "qualified other practitioners," neither of which includes registered nurses).

While qualified providers who have obtained the proper legal authority (waivers under DATA 2000) may prescribe suboxone to patients under the Massachusetts model, the "nurse care managers" (i.e., registered nurses, bachelor of science nurses, and certified addictions registered nurses) "[p]rovide patient-centered care within the nursing license scope of practice including: initial assessment and intake, induction, stabilization, and maintenance phases of treatment." Id. at 6. At Advance, Drake, a co-owner of Advance who possessed no medical training or background, conducted patient screenings over the phone (Dkt. No. 372 at 217, 372-73, 375, 378-79); and Jackson, a registered nurse, conducted patient intakes (Dkt. No. 372 at 218-19). If a doctor, such as Naum, was not present for a patient's first visit, Jackson went ahead and prescribed up to 16mg of suboxone. Id. at 252, 367. Significantly, unlike the Massachusetts model, which limited registered nurses to "assist[ing] with prescription processing, refills, prior authorizations, and insurance issues" (Dkt. No. 276-6 at 6), Jackson not only conducted patient intakes, but also issued

prescriptions for suboxone, and made dosing decisions despite no training or legal authority to do so.

Furthermore, candidates for treatment in the Massachusetts model "must have a *DSM-5* diagnosis of Opioid Use Disorder" and must have "been assessed by the treatment team and deemed appropriate for medication treatment in an office based setting." Id. at 8 (emphasis added). None of the patients at Advance had a DSM-V diagnosis of opioid use disorder documented in their chart (Dkt. No. 372 at 562-63). Equally troubling, most of the patients were deemed appropriate for suboxone treatment not by Naum but by Jackson, who conceded that she could not "articulate . . . the criteria for diagnosing an opiate addiction," id. at 223, and Drake, who had no medical training at all, id. at 372-73. This is hardly the "treatment team" envisioned by the Massachusetts model.

The Massachusetts model also requires mandatory toxicology screening and pregnancy testing at the initial intake (Dkt. No. 267-6 at 9). Neither was conducted at Advance. Moreover, it "strongly" recommends HIV testing and other clinical laboratory tests, including "complete blood count, comprehensive metabolic panel, hepatic function, pregnancy test, RPR, [and] hepatitis A, B and C serologies" (Dkt. No. 267-6 at 9). No such testing was done at Advance.

Under the Massachusetts model, it is only after the initial intake, which includes a discussion of the treatment agreement and program expectations, id. at 9-10, that the patient meets with a qualified provider (i.e., the provider authorized by law to dispense or distribute suboxone) to "[l]ay[] the groundwork for a therapeutic relationship with the patient," id. at 11. There, the qualified provider conducts a further review of the patient's "medical, mental health and substance abuse histories," a "physical examination if needed," a "review of laboratory test results," and, most importantly, confirms the "*DSM-5* diagnosis of moderate to severe Opioid Use Disorder . . . ." Id.

Although not discussed in detail in the excerpt of the Boston Medical Center guidelines filed on the Court's electronic docket (Dkt. No. 276-6), the Massachusetts model also requires patients to go through an "induction," where the patient, who is in the early stages of withdrawal, takes the suboxone at the office while he or she is supervised by the nurse care manager for proper administration. See Boston Medical Center OBAT Clinical Guidelines 18-19, https://bmcobat.org/resources/?category=1 (last visited Sept. 26, 2019). This model also allows for prescription refills, which "will increase to two week prescriptions with up to four refills" as the patient stabilizes (Dkt. No. 267-6 at 14).

Significantly, the patient is required to see the qualified provider for follow-up visits at least "once every four months." Id. at 11).

No such follow up and monitoring ever occurred at Advance. The differences in practice are stark. Naum authorized Jackson to issue prescriptions to patients although she had neither the legal authority nor the training to diagnose opioid use disorder. He allowed her to make dosing decisions in contravention of his written instructions, and to prescribe for patients whom he had never seen. If he did see a patient, he rarely saw them more than once and did not establish an ongoing doctor-patient relationship. Furthermore, Advance did not accept insurance for treatment services, nor did it authorize prescription refills. Every patient was required to pay by cash or credit card at each visit in order to obtain a prescription.

The evidence at trial thus established that Naum's practice did not, even remotely, resemble the Massachusetts model. Naum's argument that it was a model which he attempted to replicate at Advance is unsupported by any evidence and was properly excluded.

Even if the Court erred by excluding the Massachusetts model, such error was harmless and did not affect Naum's substantial rights. See Fed. R. Crim. P. 52(a) ("Any error, defect,

irregularity, or variance that does not affect substantial rights must be disregarded."); United States v. Johnson, 617 F.3d 286, 292 (4th Cir. 2010) (noting that "[e]videntiary rulings are subject to harmless error review under Federal Rule of Criminal Procedure 52"). Indeed, given the stark differences between Naum's practices at Advance and the Massachusetts protocol, excluding it from evidence had little, if any, effect on the outcome of the proceeding. See Johnson, 617 F.3d at 292 (explaining that an evidentiary ruling is harmless if "the judgment was not substantially swayed by the error"); see also United States v. Olano, 507 U.S. 725, 734 (1993) (explaining that, to affect substantial rights, the error "must have affected the outcome of the district court proceedings"). This is especially so where, as here, the evidence of guilt is strong. See, e.g., United Sates v. Harpel, 493 F.2d 346, 352 (10th Cir. 1974) ("An error possibly prejudicial does not require reversal if the evidence of defendant's guilt is strong." (citation omitted)); see also United States v. Davis, 657 F.2d 637, 640 (4th Cir. 1981) ("In considering the harmlessness of the error, it is proper to consider other evidence of the defendant's guilt.").

In sum, the Court properly excluded evidence of the Massachusetts model from trial and doing so did not prejudice Naum

or preclude him from establishing his good-faith defense. Even if it the Court erred by excluding this evidence, the error is harmless because it did not affect Naum's substantial rights.

IV. CONCLUSION

For the reason discussed, the Court **DENIES** Naum's motion for a new trial (Dkt. No. 345).

It is so **ORDERED**.

The Court **DIRECTS** the Clerk to transmit copies of this Order to counsel of record and all appropriate agencies.

DATED: October 2, 2019.

/s/ Irene M. Keeley
IRENE M. KEELEY
UNITED STATES DISTRICT JUDGE